RESPONSE

Claims 15-19, 22-41, and 61-65 are pending in the present application. Applicants appreciate the Examiner's indication that Claims 16-19, and 22 are allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims. However, for the present, Applicant respectfully declines the opportunity to rewrite these claims in independent form but reserves the right to do so at a future time.

The Specification has been amended to correct for spelling errors. Claims 15, 16, 18, 23, 26-31 36-41, and 65 were amended to more clearly define the invention. The amendments are supported in the Specification as further describe below. No new matter has been added.

Attached hereto is a marked-up version of the changes made to the specification and claims by the current amendment. The attached page is captioned "**Version with markings to show changes made.**"

Information Disclosure Statement

The Examiner stated "with respect to the IDS of 15-14-01, the references not considered on the 1449 have not been considered because they were not of record in the parent case and no copy was provided for the examiner to review." Attached please find an IDS including copies of the references not considered on the 1449 of 15-14-01. Applicants respectfully request the Examiner to consider the prior art and initial the 1449.

35 U.S.C. §132 Objection

The subject matter of Claim 34 stands objected because "[t]he added material is not supported by the original disclosure." This objection is respectfully traversed. The original Specification supports the subject matter of Claim 34.

Claim 34 recites:

> "The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 25, wherein the ejected pledget expands more quickly when wetted than a pledget of dry sponge material."

Claim 34 is supported in the Specification on page 17, lines 23-27 that states "[I]n contrast, a dry piece of sponge material does not swell until the blood has sufficiently saturated the sponge material, which can take up to hours. The hydrated and kneaded sponge material will expand to a larger size much more quickly when wetted than a piece of dry sponge material when wetted." Withdrawal of the objection is respectfully requested.

37 C.F.R. §1.71 Rejection

The Specification stands "objected to under 37 CFR 1.71 because the specification as originally filed fails to provide support for the subject matter of claim 34." This objection is respectfully traversed.

As stated above, the subject matter of claim 34 is supported in the Specification on page 17, lines 23-27 that states "In contrast, a dry piece of sponge material does not swell until the blood has sufficiently saturated the sponge material, which can take up to hours. The hydrated and kneaded sponge material will expand to a larger size much more quickly when wetted than a piece of dry sponge material when wetted." Withdrawal of the objection is respectfully requested.

35 U.S.C. §112 Rejection

Claim 34 stands "rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 34 is rejected for the same reasons as set forth in the objection to the specification under 37 CFR 1.71." This rejection is respectfully traversed for the same reasons as above. Thus, withdrawal of the rejection is respectfully requested.

37 CFR §1.75(d)(1) and MPEP §608.01(o) Objection

Claim 19 stands "objected to as failing to provide antecedent basis for the claimed subject matter" because "[t]he examiner could not locate where in the specification antecedent basis could be found." This objection is respectfully traversed.

Antecedent basis for Claim 19 can be found in the Specification on page 11, lines 22-27 and page 12, lines 1-11. Withdrawal of the objection is respectfully requested.

35 U.S.C. §102(b) Rejection

Claims 15, 23-29, 33-39, 61, and 63-65 stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Brenneman, et al. (U.S. Patent No. 5,645,566). This rejection is respectfully traversed.

According to the M.P.E.P. § 2131, "a claim is anticipated [under 35 U.S.C. § 102(b)] only if each and every element as set forth in the claim is found, either expressly or

inherently described, in a single prior art reference." *See also* Verdegaal Bros. v. Union Oil Co. of California, 814 F.2d 628, 631, 2 USPQ2d 1051, 1053 (Fed. Cir. 1987).

Claim 15, 25, 35, and 61

Claim 15, 25, 35, and 61 provide for "loading an introducer with a pledget of sponge."

Brenneman, et al. teaches an embodiment of "a foam pad compression element **74** attached to the catheter distal end **34**. The foam pad element **74** is [then] compressed when enclosed within the introducer **12**." (Col. 7, lines 17-22). Brenneman, et al. does not teach loading an introducer with a pledget of sponge, but rather teaches attaching the pledget to the distal end of a catheter and then inserting the catheter into the introducer. Thus, Brenneman, et al. can not be said to anticipate the claimed invention since it does not teach loading the introducer with a pledget as presently claimed in claims 15, 25, 35, and 61. Withdrawal of this rejection is respectfully requested.

Claims 25, 35, and 61

Claims 25, 27-35, 37-41, and 61-65 also stand rejected under 35 U.S.C. §102(b) as being allegedly anticipated by Janzen (U.S. Patent No. 5,391,183). This rejection is respectfully traversed.

Claims 25, 35, and 61 provide for:

"loading an introducer with a pledget of sponge;
loading the introducer over a guidewire positioned in the blood vessel by inserting the guidewire through the loaded pledget; and
ejecting the pledget adjacent the puncture in the wall of the blood vessel . . ."

As provided in the Specification, a user places the pledget into the introducer or alternatively, the introducer may be provided preloaded with a prepared pledget. (Specification, page 10, lines 15-20). In either case, the introducer is then advanced down through the skin and subcutaneous tissue. (Specification, page 11, lines 16-21). Thus, the pledget is loaded in the introducer before the introducer is loaded over a guidewire or into the skin of the patient.

Janzen teaches the use of "a plunger . . . to push plug 93 into and through sheath 45 until the plug exits the sheath." (Col. 9, lines 27-29). The plug is pushed through the sheath after the sheath is positioned in the tissue channel. (Col. 9, line 23). Thus, Janzen merely teaches how to push a plug through a sheath after the sheath is in the tissue channel and does not teach loading an introducer with a pledget before the introducer is into the skin of the patient.

Since Janzen does not teach or disclose all the limitations of the claimed invention, it can not anticipate the claimed invention. Withdrawal of this rejection is respectfully requested.

Remaining Independent and Dependent Claims

All dependent claims depend from independent Claims 15, 25, 35, or 61 and thus include the limitations of their respective corresponding base claim. The base claim being allowable, the dependent claims must also be allowable.

In view of the foregoing, it is respectfully asserted that the claims are now in condition for allowance.

Request for Allowance

It is believed that this Response places the above-identified patent application into condition for allowance. Early favorable consideration of this application is earnestly solicited.

If, in the opinion of the Examiner, an interview would expedite the prosecution of this application, the Examiner is invited to call the undersigned attorney at the number indicated below.

Respectfully submitted,
THELEN REID & PRIEST, LLP

Dated: 9/3, 2002

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In The Specification:

The paragraph beginning on page 7, line 16 was amended as follows:

Once the pledget 40 has been inserted into the staging chamber 34 of the introducer 12, a conventional syringe 50 containing a hydrating fluid is connected to the luer fitting 42, as shown in FIG. 4. The pledget 40 is then hydrated within the staging chamber 34 by injecting a fluid into the staging chamber from the syringe 50 causing the pledget to swell, partially or fully blocking the lumen of the introducer. The partial hydration or wetting of the exterior surface of the pledget 40 creates a lubricous surface on the pledget. The hydrated pledget 40 is then forced into [he] the delivery chamber 36 by injecting additional fluid with the syringe 50 to force the pledget through the tapered section 38 to the delivery chamber. For a somewhat smaller pledget 40, which does not entirely block the lumen of the introducer 12 after hydrating, the venture effect will help to draw the pledget into the delivery chamber 36. As shown in FIG. 5, a finger may be placed over the distal end of the introducer 12 during delivery of the pledget 40 to the delivery chamber 36 to prevent the pledget from being ejected from the introducer by the pressure of the fluid. Preferably, one or more vent holes 46 are provided in the side walls of the introducer adjacent the distal tip to allow air and liquid to escape from the introducer while the pledget 40 is positioned for delivery. These vent holes 46 are small enough to prevent the pledget 40 from passing substantially into the vent holes.

In The Claims:

Claims 15, 16, 18, 23, 26-31, 36-41, and 65 have been amended as follows:

15. (Twice Amended) A method for facilitating hemostasis of a puncture in the wall of a blood vessel, the method comprising:

establishing a depth of a blood vessel puncture of a patient;

loading an introducer with a [an] sponge pledget by hydrating and compressing the pledget;

loading the introducer over a guidewire positioned in the blood vessel by inserting the guidewire through the hydrated and compressed pledget; and

ejecting the pledget adjacent the blood vessel puncture to facilitate hemostasis while maintaining the guidewire in place.

16. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 15, wherein [the step of] establishing a depth of a blood vessel is performed by introducing a tract dilator into a tissue tract until a distal end of the tract dilator abuts an exterior of the blood vessel wall.

18. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 15, wherein [the step of] establishing a depth of a blood vessel is performed by introducing the introducer over the guidewire and into a tissue tract until a distal end of the introducer abuts an exterior wall of the blood vessel.

23. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 15, wherein [the step of] loading the introducer includes injecting fluid into the introducer to hydrate and compress the pledget.

26. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 25, wherein [the step of] loading the introducer involves hydrating and loading the pledget into the introducer.

27. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 25, wherein [the step of] loading the introducer involves compressing and loading the pledget into the introducer.

28. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 25, wherein [the step of] loading the introducer over the guidewire involves piercing the pledget with the guidewire.

29. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 25, further comprising [the step of] establishing a depth of the puncture in the wall of the blood vessel.

30. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 29, wherein [the step of] establishing a depth of a puncture is performed by introducing a tract dilator into a tissue tract until a distal end of the tract dilator abuts an exterior of the blood vessel wall.

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31. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 29, wherein [the step of] establishing a depth of a puncture is performed by introducing the introducer over the guidewire and into a tissue tract until a distal end of the introducer abuts an exterior wall of the blood vessel.

36. (Once Amended) The method for advancing a pledget of sponge through the skin and subcutaneous tissue overlying a puncture in the wall of a blood vessel according to claim 35, wherein [the step of] loading the introducer involves hydrating and loading the pledget into the introducer.

37. (Once Amended) The method for advancing a pledget of sponge through the skin and subcutaneous tissue overlying a puncture in the wall of a blood vessel according to claim 35, wherein [the step of] loading the introducer involves compressing and loading the pledget into the introducer.

38. (Once Amended) The method for advancing a pledget of sponge through the skin and subcutaneous tissue overlying a puncture in the wall of a blood vessel according to claim 35, wherein [the step of] loading the introducer over the guidewire involves piercing the pledget with the guidewire.

39. (Once Amended) The method for advancing a pledget of sponge through the skin and subcutaneous tissue overlying a puncture in the wall of a blood vessel according to claim 35, further comprising [a step of] establishing a depth of the puncture in the wall of the blood vessel.

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40. (Once Amended) The method for advancing a pledget of sponge through the skin and subcutaneous tissue overlying a puncture in the wall of a blood vessel according to claim 39, wherein [the step of] establishing a depth of the puncture is performed by introducing a tract dilator into the subcutaneous tissue until a distal end of the tract dilator abuts an exterior of the blood vessel wall.

41. (Once Amended) The method for advancing a pledget of sponge through the skin and subcutaneous tissue overlying a puncture in the wall of a blood vessel according to claim 39, wherein [the step of] establishing a depth of the puncture is performed by introducing the introducer over the guidewire and into the subcutaneous tissue until a distal end of the introducer abuts an exterior wall of the blood vessel.

65. (Once Amended) The method for facilitating hemostasis of a puncture in the wall of a blood vessel according to claim 61, wherein [the step of] ejecting the pledget is performed by withdrawing the introducer.